K124048

JAN 29 2013

6. *510(k) Summary*

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Intuitive Imaging Informatics, LLC
DATE PREPARED:	17 July 2012
CONTACT PERSON:	Cindy Simoni Intuitive Imaging Informatics, LLC 30 Hackamore Lane, STE 6 Bell Canyon, CA 91307 Phone: 818.347.8909, x110 Fax: 888.908.6242
TRADE NAME:	ImageQube
CLASSIFICATION NAME:	System, Imaging Processing
DEVICE CLASSIFICATION:	Class II
REGULATION NUMBER	892.2050
PRODUCT CODE	LLZ
PREDICATE DEVICES:	ImageQube (K051037) Amicas PACS 6.0 (K082144) Candelis ImageGrid (K080333) Synapse Obliquus MIP/MPR/Fusion (K100881)

Substantially Equivalent To:
The ImageQube is substantially equivalent in intended use, principal of operation and technological characteristics to the current marketed ImageQube, Amicas PACS 6.0, Candelis ImageGrid and Synapse Obliquus MIP/MPR Fusion devices.

Description of the Device Subject to Premarket Notification:

ImageQube is designed for use by a physician or other medical professionals in the acquisition of medical images and demographic detail from all institutional imaging modalities, including, but not limited to CT, MRI, NM, DR, US, PET Fusion, Angio and MG (including display of DICOM overlay and 3D Mammography images), along with secondary capture devices, such as film digitizers or other imaging sources. The acquired medical images and demographic information may be displayed, processed, reviewed, sent to and retrieved by radiologists at remote sites, stored, archived or printed. Multi-planar Reconstruction (MPR), Anatomic Triangulation (AT), Dynamic Cross-

Referencing, Maximum Intensity Projection (MIP), Slab and 3D display are also available for optional use.

Indication for Use:

ImageQube is intended for use by a physician or other medical professionals in the display and interpretation of medical images and demographic detail from all institutional imaging modalities, including, but not limited to, CT, MRI, NM, DR, US, PET Fusion, Angio and MG (including display of DICOM overlay and 3D Mammography images), along with secondary capture devices, such as film digitizers or other imaging sources. The ImageQube is designed for display, interpretation, storage and distribution of all modalities.

Only pre-processed DICOM For Presentation images can be interpreted for primary diagnosis in mammography. Lossy compressed mammographic images and digitized film screen images must not be viewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor meeting all the technical specifications required by the FDA for the Performance of Screening and Diagnostic Mammography. Images that are printed to film must be done using an FDA-approved printer for the diagnosis of digital mammography images. Efficient mammography screening makes toolbars and thumbnails available on each monitor, while also handling DICOM overlay display.

Acquired medical images may be displayed and manipulated further utilizing Multi-Planar Reconstruction (MPR), Anatomic Triangulation (AT), Dynamic Cross-Referencing, Maximum Intensity Projection (MIP), Slab and 3-D display, sent to and retrieved by radiologists in-house at facilities or at remote sites, stored, archived or printed. The ImageQube can operate as an independent device, or can also be interfaced with Rational Imaging PACS systems. Annotated print pages, transcribed reports and Key Image Summaries can also be accessed.

Technological Characteristics:

The ImageQube has the same technological characteristics and is similar in overall design, principal of operation and configuration compared to the predicates. The table below illustrates the similarities and differences in Technological Characteristics between the devices.

	Modified ImageQube	**ImageQube (K051037)**	**Amicas PACS 6.0 (K082144)**	**Candelis ImageGrid (K080333)**	**Synapse Obliquus MIP/MPR/ Fusion (K100881)**
Use					
Storing, distributing, displaying,	Yes	Yes	Yes	Yes	Yes

	Modified ImageQube	ImageQube (K051037)	Amicas PACS 6.0 (K082144)	Candelis ImageGrid (K080333)	Synapse Obliquus MIP/MPR/ Fusion (K100881)
analyzing, manipulating and enhancing of images					
Standards					
DICOM (data exchange)	Yes	Yes	Yes	Yes	Yes
JPEG (image compression)	Yes	Yes	Yes	Yes	Yes
Features					
Maximum Intensity Projection (MIP)	Yes	No	Yes	Yes	Yes
Multiplanar Resolution (MPR)	Yes	No	Yes	Yes	Yes
DICOM Overlay	Yes	No	Yes	Yes	No
PET/CT Fusion	Yes	No	No	Yes	Yes
Slab	Yes	No	Yes	Unknown	Unknown
Critical Results	Yes	No	Yes	Unknown	Yes
Mammography	Yes	No	Yes	Yes	No
Peer Review	Yes	No	Unknown	Unknown	Yes

Performance

Support of the substantial equivalence of the ImageQube device was provided as a result of software validation, which confirms all features of the ImageQube device were compliant with the software requirements.

Basis for Determination of Substantial Equivalence:

Upon reviewing and comparing intended use, design, principle of operation and overall technological characteristics, the ImageQube is determined by Intuitive Imaging Informatics, LLC to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 29, 2013

Intuitive Imaging Informatics, LLC
c/o Mr. Jeff D Rongero
Senior Project Manager
12 Laboratory Drive
RESEARCH TRIANGLE PARK NC 27709

Re: K124048
Trade/Device Name: ImageQube
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 21, 2012
Received: December 31, 2012

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

5. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: **ImageQube**

Indications for Use:
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AND/OR

Prescription Use __X___ (21 CFR 801 Subpart D)

Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices and Radiological Health (OIR)

Division Sign-off

Office of In Vitro Diagnostic Device
Evaluation and Safety
510k K124048